

### **REMARKS**

Claims 1-2, 4-9, 11-23, and 25-27, as amended, and new claims 28-30 are pending in the application for the Examiner's review and consideration. Claim 1 was amended to recite that the composition includes a manganese component (*See, e.g.*, Specification, page 15, lines 26-28 and original claim 10). Claim 1 was also amended to recite that the acidic moisturizing agent can be tannic acid (*See, e.g.*, Specification, page 13, lines 11-12). Claim 5 was amended to correct a typographical error wherein "ceramide" was mis-spelled. Claim 7 was amended to recite that the dermatological agent of claim 1 further comprises a moisturizing agent selected from the group consisting of primrose oil, omega 3 gamma-linolenic acid, flax seed oil, and mixtures thereof (*See, e.g.*, Specification, page 15, lines 15-18). Claim 11 was amended to only recite an amount of a manganese compound since claim 11 depends from claim 1 and claim 1, as amended, only recites a manganese compound. Claim 11 was also amended to delete the language "if present." Claim 16 was amended to replace the phrase "vitamin E source" with --vitamin E or a source of vitamin E-- (*See, e.g.*, Specification, page 19, lines 12-23). Similarly, claim 21 was amended to replace the phrases "vitamin A source," "vitamin E source," and "silymarin source" with --vitamin A or a source of vitamin A--, --vitamin C or a source of vitamin C--, and --silymarin--, respectively. New claim 30 merely rewrites canceled claim 24 in dependent form. As no new matter has been added, Applicant respectfully submits that these amendments be entered. Applicant respectfully submits that all claims are in condition for allowance

### **THE INVENTION**

The invention relates to a dermatological agent comprising at least one fruit extract from pomegranate; a hydrophobic moisturizing agent; a hydrophilic moisturizing agent; a mono- or poly-hydroxy acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin; a manganese component (claim 1), a copper component (claim 28), or a selenium component (claim 29); and a pharmaceutically acceptable carrier.

### **THE REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 7, 11, 13, 15, 16, 18, and 21 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the reasons set forth on pages 2-3 of the Office Action. The Examiner alleged that claim 7 is indefinite since it requires specific moisturizing

agents without specifying if the moisturizer is a hydrophobic moisturizer or a hydrophilic moisturizer. In response Applicant has amended claim 7 to recite that the dermatological agent further comprises the specific moisturizers enumerated in claim 7 (*See, e.g.*, Specification, page 15, lines 15-18).

The Examiner alleges that claim 11 is indefinite for reciting the components that are not included in claim 1. In response Applicant has amended claim 11 to only recite the amount of the manganese component that is recited in claim 1. The Examiner further alleges that claim 11 is indefinite because of the phrase "if present." In response, Applicant has amended claim 11 to delete the phrase "if present."

The Examiner also alleges that claims 13, 15, and 18 are indefinite because of the phrase "if present." Applicant notes that the phrase "if present" is not recited in claims 15 and 18. With regard to claim 13, Applicant notes that claim 13 depends from claim 12 and that claim 12 recites "a dermatological agent comprising at least one of . . . ." Accordingly, each component recited in the Markush group itemized in claim 12 is not required in the dermatological agent. All that is required is one of the components listed in the Markush group. Therefore, claim 13 recites amounts for each of the component "if present."

The Examiner alleges that claim 16 is indefinite for reciting a "vitamin E source" as an anti-inflammatory because it is not clear if the source or the vitamin E possesses the anti-inflammatory activity. Applicant has amended claim 16 to recite that the anti-inflammatory component can be --vitamin E or a source of vitamin E--. Applicant respectfully submits that the specification fully supports vitamin E or a source of vitamin E (*See, e.g.*, Specification, page 19, lines 12-23). The specification clearly recites that vitamin E can be used to reduce or inhibit inflammation, *i.e.*, be an anti-inflammatory (*See, e.g.*, Specification, page 19, lines 13-15) and that the vitamin E can be provided by a vitamin E source (*See, e.g.*, Specification, page 19, lines 16-23). Moreover, Applicant has provided representative examples of vitamin E sources. One of ordinary skill in the art would readily understand the phrase "vitamin E source" to mean a compound that, when administered, provides vitamin E.

The Examiner alleges that claim 21 is indefinite for reciting a "vitamin A source," a "vitamin C source," and a "silymarin source," as the anti-oxidant because it is not clear if the source or the vitamin A, vitamin C, or silymarin possesses the anti-oxidant

activity. Applicant has amended claim 21 to replace the phrases “vitamin A source,” “vitamin C source,” and “silymarin source” with --vitamin A or a source of vitamin A--, --vitamin C or a source of vitamin C--, and “silymarin,” respectively. Applicant respectfully submits that the specification fully supports vitamin A or a source of vitamin A as an anti-oxidant (*See, e.g.*, Specification, page 20, lines 19-26 and page 20, lines 4-8) and vitamin C or a source of vitamin C as an anti-oxidant (*See, e.g.*, Specification, page 20, lines 19-26 and page 20, lines 14-15). Moreover, Applicant has provided representative examples of vitamin A and vitamin C sources. One of ordinary skill in the art would readily understand the phrase “vitamin A source” or “vitamin C source” to mean a compound that, when administered, provides vitamin A or vitamin C, respectively. For the above reasons, Applicant respectfully submits that the rejection of claims 7, 11, 13, 15, 16, 18, and 21 under 35 U.S.C. 112, second paragraph be reconsidered and withdrawn.

#### **THE CLAIM OBJECTIONS**

Claim 5 was objected to since the term “ceramide” was mis-spelled as “seramide.” Applicant has amended claim 5 to correctly spell the term “ceramide.” Applicant appreciates the Examiner’s recognition of this spelling error and for pointing it out. For the above reasons, Applicant respectfully submits that the objection to claim 5 be reconsidered and withdrawn.

#### **THE DOUBLE PATENTING REJECTION**

Claims 1-27 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/501,218. Initially, Applicant notes that claim 1-27 are not pending in this application. Only claims 1, 2, 4-9, and 11-27 were pending at the time of the Office Action. As this is a provisional rejection, Applicants will address the rejection when either copending Application No. 09/3501,218 or the present application is allowed.

#### **THE REJECTIONS UNDER 35 U.S.C. § 102(a)**

Claims 24-27 were rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,985,300 to Crotty et al. (“Crotty”) for the reasons set forth on page 3 of the Office Action. Applicant respectfully traverses the rejection.

Crotty discloses a cosmetic product that is an adhesive strip to remove keratotic plugs and to deliver active ingredients to the skin (*See, e.g.*, Crotty, column 2, lines 40-42). A variety of active ingredients are disclosed.

Crotty, however, fails to disclose a manganese component as recited in claim 24, as amended. Crotty is completely silent as to a manganese component. Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, Applicant respectfully submits that Crotty does not anticipate claims 24-27, as amended. For the above reasons, Applicant respectfully requests that the rejection under 35 U.S.C. 102(a) be reconsidered and withdrawn.

**THE REJECTIONS UNDER 35 U.S.C. § 103(a)**

Claims 1, 2, 4-9, and 11-27 were rejected under 35 U.S.C. § 103(a) as being obvious over Crotty in view of by U.S. Patent No. 5,571,503 to Mausner ("Mausner") for the reasons set forth on pages 5-7 of the Office Action. Applicant respectfully traverses the rejection.

Mausner discloses a cosmetic composition comprising water and, emulsified in the water, (1) an anti-pollution complex, (2) a micellar complex, (3) an anti-free radical complex, and (4) a sunscreen (*See, e.g.*, Mausner, column 1, lines 46-58). The compositions provide protection from environmental pollution, protect from ultraviolet light and free radicals, and moisturize the skin (*See, e.g.*, Mausner, column 1, lines 34-38).

As discussed above, Crotty fails to disclose or suggest a dermatological agent comprising at least one fruit extract from pomegranate in combination with a hydrophobic moisturizing agent, a hydrophilic moisturizing agent, and a mono- or poly-hydroxy acid moisturizing agent and a manganese component, as presently claimed. There is absolutely no disclosure or suggestion in Crotty of a manganese component as recited in independent claim 1, as amended. Similarly, there is absolutely no disclosure or suggestion in Crotty of a copper component or a selenium component as recited in new claims 28 and 29. These are important components of the composition. For example, the manganese component is the co-factor used by the natural enzymatic antioxidant SOD found in mitochondria and, thus, facilitates this mechanism of antioxidation (*See, e.g.*, Specification, page 16, lines 29-31 and page 20, lines 21-25) and the copper component inhibits elastase and, thus, assists in treatment of

elastic tissue defects (*See, e.g.*, Specification, page 16, lines 14-15). Indeed, Crotty does not even mention these components.

Mausner fails to remedy the deficiencies in Crotty. Mausner, similar to Crotty, is completely silent as to a manganese component as recited in claim 1, as amended, or the copper component or selenium component, as recited in new claims 28 and 29. Indeed, Mausner does not even mention these components. As discussed above, however, these are important components of the invention. Applicant respectfully submits that neither Crotty nor Mausner, alone or in combination, render the claimed dermatological agent obvious. For the above reasons, Applicant respectfully requests that the rejection under 35 U.S.C. 103(a) be reconsidered and withdrawn.


With regard to all claims not specifically mentioned, these are believed to be allowable not only in view of their dependency on their respective base claims and any intervening claims, but also for the totality of features recited therein.

All claims are believed to be in condition for allowance. Should the Examiner disagree, Applicant respectfully invites the Examiner to contact the undersigned attorneys for Applicant to arrange for an in-person interview in an effort to expedite the prosecution of this matter.

No fee is believed to be due for the amendments herein. Should any fee be required, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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Enclosure

**APPENDIX A**  
**MARKED UP VERSIONS OF THE AMENDED CLAIMS**

Application No.: 09/501,217; Filed: February 10, 2000

1. A dermatological agent for managing a dermatological condition in a patient comprising:

at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals;

a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a mono- or poly-hydroxy acid or tannic acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin;

a [cysteine] manganese component; and

a pharmaceutically acceptable carrier.

5. (Amended) The dermatological agent of claim 3, wherein the hydrophobic agent is selected from the group consisting of ceramide [seramide], borage oil, tocopherol linoleate, dimethicone, glycerine, and mixtures thereof.

7. (Amended) The dermatological agent of claim 1, further comprising a [wherein the] moisturizing agent [is] selected from the group consisting of primrose oil, omega 3 gamma-linolenic acid, flax seed oil, and mixtures thereof.

11. (Amended) The dermatological agent of claim 1, wherein [the cysteine component, if present, is N-acetyl cysteine and is present in an amount from about 1 to 10 weight percent, the magnesium component, if present, is magnesium ascorbate and is present in an amount from about 1 to 10 weight percent, wherein the magnesium is present in an amount from about 10 to 30 weight percent of the complex,] the manganese component[, if present,] is manganese ascorbate and is present in an amount from about 0.5 to 10 weight

percent, wherein manganese is present in an amount from about 5 to 20 weight percent of the complex[, or the copper component, if present, is copper sebacate and is present in an amount from about 0.01 to 5 weight percent, wherein the copper is present in an amount from about 5 to 20 weight percent of the complex].

16. (Amended) The dermatological agent of claim 14, wherein the anti-inflammatory component is selected from the group consisting of vitamin E or a source of vitamin E [source], a transition metal component, aloe vera gel, aloe vera, licorice extract, pilewort, Canadian willow root, zinc, allantoin, and mixtures thereof.

21. (Amended) The dermatological agent of claim 20, wherein the antioxidant is selected from the group consisting of a catechin-based preparation, vitamin A or a source of vitamin A [source], a ginkgo biloba extract, [a] silymarin [source], a quercetin compound, vitamin C or a source of vitamin C [source], a carotenoid, and mixtures thereof.